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REMARKS/ARGUMENTSPreliminary matters

Upon review of the application as filed, the undersigned became aware of a clerical oversight in the mis-numbering of the claims wherein no claims numbers 31 and 32 were presented. Therefore, the undersigned is of the belief that originally presented claims 33 and 34 have been renumbered to be claims 31 and 32 per MPEP 608.01(j) and 37 C.F.R. § 1.126.

Applicants thank the Office for the renumbering to correct the oversight.

Prior art rejection under 35 U.S.C. § 103(a)

Claims 1-32 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Stewart et al. (WO 98/34644). Applicants have carefully reviewed the cited reference as well as the statement of the rejection and traverse as follows.

Given the citation of a single reference in the instant rejection, three critical criteria must be present for a *prima facie* case of obviousness. There must be 1) a motivation to modify the cited reference to arrive at the claimed invention; 2) a reasonable expectation of success in such a modification; and 3) a teaching or suggestion of all claim limitations. These three criteria are part of the well settled body of case law for establishing a case of obviousness as set forth by the Court of Appeals for the Federal Circuit ("Federal Circuit") and its predecessor, the Court of Customs and Patent Appeals (CCPA). Applicants respectfully submit that none of these criteria have been met in the instant case. Therefore, Applicants submit that no *prima facie* case of obviousness has been presented. Moreover, Applicants note that the disclosure of Stewart et al., if applied as asserted in the statement of the rejection, would actually lead away from the instantly claimed invention.

The statement of the rejection essentially sets forth the position that because Stewart et al. allegedly discloses the use of photosensitizing agents to reduce or prevent the effects of inflammation in an injured tissue, it would have been obvious to reduce or prevent inflammation *per se* caused by photodynamic therapy (PDT) with the same photosensitizing agent with a reduced light

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dose following a normal light dose. This is despite *the complete absence of any prior art teaching, suggestion or indication*

- 1) *motivating the use of low dose light following a normal PDT protocol or*
- 2) *giving rise to a reasonable expectation of success.*

In the absence of the above, Applicants respectfully submit that the instant rejection is based upon an impermissible "obvious to try" standard. Moreover, the cited reference, and the statement of the rejection, provides no basis for the concept of low dose light following a normal dose of light.

The instantly claimed invention is conceptually relatively simple. Following the administration of normal, or standard, dose PDT to a tissue area of a subject, the treated area, or a portion of the subject that overlaps with the treated area, is exposed to low dose light *without the further addition of photosensitizing agent*, to reduce or prevent inflammation *per se*.

Stewart et al., however, is directed to administering a photosensitizing agent to an injured tissue followed by low dose light which reduces or prevents the effects of inflammation in the injured tissue. As the statement of the rejection recognizes, there is no disclosure or suggestion of "injured tissue" as encompassing tissue that has been treated by PDT. To the contrary, the sentence bridging pages 16 and 17 of Stewart et al. describes how the *therapeutic* use of PDT has been observed to cause inflammation. Applicants respectfully submit that such therapeutically treated tissue would not be within the scope of "injured tissue" as disclosed and discussed by Stewart et al.

Despite the above, the statement of the rejection asserts that

"It would have been obvious to a person skilled in the art to employ a compound known for the treatment of inflammation and use of for the treatment of inflammation caused by photodynamic therapy.

One skilled in the art would have been motivated to employ the teachings of the above reference [Stewart et al.], since it relates to the use of the claimed compounds for the treatment of inflammation. To

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use a well known anti inflammatory agent *for the treatment of any type of inflammation would have been obvious* to a person skilled in the art in the absence of evidence to the contrary." (emphasis added, see pages 2-3 of the Action)

As evident from the above, however, motivation for the modification of Stewart et al. to be within the instant claims arises from an assertion that the existence of a "well known anti inflammatory agent" is sufficient to lead to the treatment of "any type of inflammation", including the particular method as claimed. Stated differently, the motivation is based upon the premise that an ordinary artisan would use, without hesitation, any known anti inflammatory agent for any situation of inflammation. This asserted motivation, however, is neither disclosed nor suggested by the cited references, alone or in combination.

Moreover, the asserted motivation must be modified from that presented in the statement of the rejection in that it is not the "well known anti inflammatory agent" *per se* that is alleged to be taught by Stewart et al., but rather a modified PDT protocol that is efficacious against *the effects of inflammation*. Therefore, factually, Stewart provides a method, rather than an agent, that acts against the effects of inflammation rather than inflammation.

Therefore, and contrary to the statement of the rejection, the teachings of Stewart et al. (concerning the use of a modified PDT protocol to reduce or prevent the effects of inflammation in injured tissue) is not the same as the claimed methods. While the claimed methods relate to the reduction or prevention of inflammation in tissues already treated with standard PDT, Stewart et al. wholly fails to include such previously treated tissue as an "injured tissue" within the scope of their disclosure. While the standards for a *prima facie* case of obviousness requires that this deficiency in the disclosure be remedied, *the statement of the rejection provides no basis for why* an artisan of ordinary skill would modify the teachings of Stewart et al. to include tissue treated with standard PDT as an "injured tissue".

In the absence of a reason *why*, Applicants respectfully submit that the rejection is deficient for failing to provide an adequate motivation to modify Stewart et al. to arrive at the

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claimed invention. The Federal Circuit has reiterated that there are three possible sources for a motivation to modify the teachings of a reference: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998). As noted above, however, the rejection is not supported by a motivation that originates from any of these sources. The nature of the problem, to reduce or prevent inflammation resulting from normal or standard PDT treatment, certainly does not lead the ordinary artisan to the use the methods of the instant claims. The teachings of Stewart et al. similarly do not provide motivation for any modification. And finally, there is no evidence to support the notion that the knowledge of the ordinary artisan would motivate the modification of Stewart et al.

Appellants further note that the facts of the instant application are analogous to the facts in *In re Fine* (837 F2d. 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). The claims in *Fine* were directed to a system for detecting and measuring nitrogen compounds by use of gas chromatography and a nitric oxide detector. The primary reference (Eads) cited against the claims disclosed a system for monitoring sulfur compounds by use of gas chromatography and a device to calculate the concentration of sulfur compounds based on the amount of sulfur dioxide. This is analogous to Stewart et al., who disclose the use of a modified PDT protocol to treat the effects of inflammation in tissues while the instant invention is directed to treating *inflammation in different tissues following standard PDT treatment*. The secondary reference in *Fine* disclosed a nitric oxide detector in an attempt to fulfill the requirement for the necessary modification of the primary Eads reference. This is analogous to the assertion (in the instant statement of the rejection) of treating the tissue already treated with standard PDT. The Federal Circuit held the assertion that "substitution of one type of detector for another in the system of Eads would have been within the skill of the art" as **insufficient** without support or explanation of the conclusion.

The Federal Circuit's view is directly applicable to the facts of the instant case, where there is no support or explanation of why the ordinary artisan would have selected tissue inflamed by standard PDT treatment as subject for use with the disclosure of Stewart et al. The disclosure of Stewart et al. with respect to the nature of the "injured tissue" does not contemplate or suggest tissue

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treated with standard PDT. The particular forms of "injured tissue" described by Stewart et al. do not relate to standard PDT therapy (see page 19, lines 5-9 therein). There is no suggestion in Stewart et al. or any other source presented in the statement of the rejection to consider tissue treated with standard PDT as "injured tissue". Therefore, no motivation to modify the teachings of Stewart et al. as alleged has been presented as required by law.

Even if the teachings of Stewart et al. were viewed, as alleged in the above quote from the Office Action, as indicating that the protocol of Stewart et al. is sufficient to lead to the treatment of multiple indications of inflammation, Applicants respectfully submit that this would still be insufficient to render the claimed invention obvious in light of *In re Baird* (29 USPQ2d 1550 (Fed. Cir. 1994)) and related holdings in *In re Deuel* (34 USPQ2d 1210 (Fed. Cir. 1995)), *In re Bell* (26 USPQ2d 1529, 1532 (Fed. Cir. 1993)) and *In re Jones* (21 USPQ2d 1941 (Fed Cir. 1992)).

The teachings of Stewart et al. are insufficient because they only disclose the concept of a modified PDT protocol that may be used to reduce or prevent inflammation in injured tissue. But even with the assertions in the instant statement of the rejection, this can be, at most, no more than an assertion of the ability to use a method to treat a genus of diverse tissues subject to inflammation. This disclosure of a genus as well as a number of species (treatment of different types of injured tissue) within the genus, does not include any species like, or similar to, that resulting from treating tissues previously subjected to standard PDT as in the claimed invention.

The Federal Circuit in *Baird*, *Deuel*, and *Bell* repeatedly set forth the standard that a broad genus does not render a species within the genus obvious. "No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared." *Deuel*, 51 F.3d at 1558-9, 34 USPQ2d at 1215; see also *Baird*, 16 F.3d at 382-3, 29 USPQ2d at 1552, and *Bell*, 991 F.2d at 784, 26 USPQ2d at 1531. Similarly, *Jones* stands for the proposition that a genus of operative embodiments known in the prior art does not render claims to a species obvious in the absence of motivation or suggestion to make the species.

Applied to the facts of the instant case, it would **not be obvious** to modify the teachings of Stewart et al. for use with tissue treated with standard PDT unless there is something in Stewart et

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al. to lead the ordinary artisan to the particular modification. Applicants respectfully submit that there is nothing in Stewart et al. that would provide such direction to the ordinary artisan. The mere description of various "injured tissues" and their causes in Stewart et al. does not necessarily lead to the instantly claimed invention. This follows because Stewart et al.'s broad genus of methods simply does not include any embodiment related to the methods of the instant invention. Moreover, the allegation of a motivation in the statement of the rejection fails to remedy this deficiency by providing evidence of the necessary suggestion or motivation. Without this necessary suggestion or motivation as required by *Baird*, *Deuel*, *Bell*, and *Jones*, the instant rejection is an impermissible hindsight reconstruction of the claimed invention using the Stewart et al. reference.

Therefore, and in light of the well settled jurisprudence exemplified by *Rouffet* and *Fine* as well as *Baird*, *Deuel*, *Bell*, and *Jones*, the instant rejection is deficient for failing to be adequately supported by motivation to modify the cited reference as required by law. While this error alone is sufficient to require withdrawal of the rejection, Applicants note that the rejection also fails to provide an adequate expectation of success.

Even a brief review of the teachings of Stewart et al. reveals that they are limited by the nature of the "injured tissue" contemplated for use with their methods. Factually, there are significant differences between the "injured tissue" described by Stewart et al. and the tissue treated by standard PDT of the instant invention. As one example of the differences, the concept of "injured tissue" in Stewart et al. appears relative to "non-injured" or "normal" tissue whereas the tissue treated with standard PDT of the instant invention relates to non-normal tissue because there is no reason to treat normal tissue with standard PDT. In fact, standard PDT protocols often include steps to avoid photoactivation of the administered photosensitizer in normal tissues.

Therefore, and contrary to the implied equivalence in the statement of the rejection, teachings relating to the "injured tissue" of Stewart et al. are not necessarily applicable to tissue treated by standard PDT of the instant invention. It is the burden of the *prima facie* case to provide objective evidence of such equivalence, and Applicants respectfully submit that non-normal tissue treated with standard PDT is not the same as "injured tissue" as provided by Stewart et al. Stated differently, application of standard PDT does not result in "injured tissue". In the absence of such

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equivalence, there would have been no expectation that Stewart et al.'s method of treating "injured tissue" can be successful in treating tissue already treated by standard PDT as claimed.

Therefore, Stewart et al., despite the allegations in the statement of the rejection, would at most support an impermissible "obvious to try" standard for obviousness. Stated differently, Stewart et al.'s results might have made it obvious to try to treat tissue already treated by standard PDT. As noted in *In re O'Farrell* (853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988)), an "obvious to try" situation exists "when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued." See *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990). This describes the instant situation exactly in that the success of Stewart et al. may pique the curiosity of the ordinary artisan to investigate whether it can be applied to tissue treated by standard PDT. But that ordinary artisan has *no expectation that successful reduction or prevention of inflammation would result.*

Finally, Stewart et al. fail to teach or suggest the important claim limitations relating to the use of low dose light following normal or standard PDT *without administration of additional photosensitizer*. This important aspect of the claimed subject matter is clearly provided for in independent claims 1 and 17 and particularly presented in independent claim 31. This aspect of the invention as claimed is not found in Stewart et al., and the statement of the rejection fails to provide any basis for its presence as required for a *prima facie* rejection. In light of this deficiency, the rejection should be withdrawn.

Additionally, a review of Stewart et al. suggests that even if their teachings were to be applied following a standard PDT treatment, it would lead to the administration of additional photosensitizer (perhaps after dissipation, removal or degradation of the photosensitizer from the standard PDT treatment) followed by the low dose PDT to reduce or prevent the effects of inflammation. This leads to methods that are wholly different from the instant invention and thus leads the ordinary artisan away from the claimed methods.

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In light of the above, Applicants respectfully submit that the legal requirements for obviousness have not been met and that the instant rejection may be properly withdrawn. Early indication to that effect and indication of the claims as allowable is urged.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket No. 273012011800. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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